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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,083	01/05/2001	Edward Green	00487.00007	4709

22907 7590 06/18/2002

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EXAMINER

RAO, MANJUNATH N

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 06/18/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/754,083

Applicant(s)

GREEN ET AL.

Examiner

Manjunath N Rao

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-26 are still at issue and are present for examination.

Applicant's election of Group I, Claims 1-16 in Paper No. 8 is acknowledged. However, upon closer review of the elected claims, Examiner found that there were more than one inventions in the elected group and hence has subjected the claims to another round of restriction. Examiner regrets any inconvenience to the applicants.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, drawn to a gram positive bacterium which has been transformed with a heterologous gene encoding pyruvate decarboxylase or a functional equivalent but has solely native alcohol dehydrogenase function, classified in class 435, subclass 252.3.
- II. Claims 14-16, drawn to a recombinant, sporulation deficient thermophilic *Bacillus* which grows at greater than 50 degree C, classified in class 435, subclass 252.3.

(Claim 14 will be examined to the extent it reads on the strains that belong to the elected group)
- III. Claims 17-20, drawn to a method of producing ethanol, classified in class 435, subclass 161.
- IV. Claim 21, drawn to a method for producing L-lactic acid, classified in class 435, subclass 139.

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- V. Claims 22-25, drawn to a nucleic acid molecule and a plasmid, classified in class 536, subclass 23.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct from each other. While the invention of group I is any gram positive bacterium which has been transformed with a heterologous gene encoding pyruvate decarboxylase or a functional equivalent but has solely native alcohol dehydrogenase function, the invention of group II is a specific sporulation deficient *Bacillus* which grows at greater than 50 degree C and does not have a heterologous gene encoding pyruvate decarboxylase. They are thus different from each other at the molecular and chemical level and have separate utilities such as the use of group I bacteria for ethanol production and the use of group II bacteria for further genetic manipulation or for lactic acid production.

Inventions I, II and III, IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of producing ethanol or lactic acid of groups III, IV can be accomplished alternatively using yeasts or by chemical synthesis methods as opposed to the methods of groups III, IV. The groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

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Inventions I, II and V are products which are patentably distinct from each other. The invention of groups I, II, V are products, bacteria and polynucleotides, which are chemically and physically different from each other and have separate utilities such as the use of bacterial cells for production of ethanol or lactic acid versus the use of polynucleotides for recombinant protein production. The groups are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

Inventions III, IV are patentably distinct from each other. The method of producing ethanol group III, the method of producing lactic acid of group IV, are all unrelated as they comprise distinct steps, utilize different products and produce different results. The groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

Inventions III, IV and V are patentably distinct from each other. The methods of groups III, IV neither makes nor uses the product of group V. They have separate utilities and are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N Rao whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m..

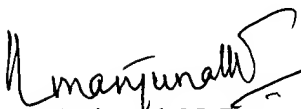
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.


Manjunath N. Rao
June 5, 2002